UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA

Plaintiff,

v.

B4B EARTH TEA LLC, a limited liability company;

B4B CORP., a corporation; and

ANDREW MARTIN SINCLAIR, individually and as an officer of B4B EARTH TEA LLC and B4B CORP.,

Defendants.

UNITED STATES' OPPOSITION TO DEFENDANT SINCLAIR'S MOTION TO RECONSIDER AND DISMISS UNITED STATES' EXPERT REPORTS AND TO ORDER THE UNITED STATES TO CONDUCT TESTING OF B4B EARTH TEA

Civil Action No.: 22-CV-1159

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I. INTRODUCTION

Defendant Andrew Martin Sinclair ("Defendant") manufactures and sells a drink called B4B Earth Tea ("Earth Tea"). He has claimed that Earth Tea can prevent, treat, and cure COVID-19 and other diseases. The United States alleges that Defendant made these health claims without competent and reliable scientific evidence to substantiate them, that they are thus deceptive claims, and that Defendant's conduct violates the Federal Trade Commission Act and the COVID-19 Consumer Protection Act.

Because Defendant makes claims that Earth Tea prevents, treats, and cures specific diseases, the United States alleges that Earth Tea is a drug under federal law. The United States also alleges that Defendant has neither sought nor received Food and Drug Administration approval to market Earth Tea, the medical community does not recognize Earth Tea as safe and effective against any disease, and therefore Defendant's interstate sale and shipment of Earth Tea is shipment of an unapproved new drug in interstate commerce in violation of the Food, Drug, and Cosmetic Act ("FDCA").

On July 30, 2024, in accord with the applicable rules and the schedule set by the Court, the United States disclosed the reports of its two experts: Dr. James P. McCormack, and Dr. Mariton Daniel Dos Santos. On September 6, 2024, the United States provided Defendant a brief supplement to Dr. Dos Santos's report.

Dr. McCormack is a college professor with a Doctorate of Pharmacy and over 140 publications in peer-reviewed journals—3 related to COVID-19 treatments and prevention—who presented over 500 seminars on drug therapy, including on COVID-19. Ex. 1 (Dr. McCormack Expert Report) at 2-3. Based on his education, training and experience, he is an expert in evidence appraisal, including the design, analysis and interpretation of clinical trials. Ex. 1 at 3.

Dr. McCormack examined whether there is competent and reliable scientific evidence that substantiates the health claims Defendant made relating to COVID-19 or any other disease. Ex. 1 at 3. Dr. Based on his professional knowledge, training, and experience, Dr. McCormack opined that, to substantiate claims that Earth Tea can treat, cure or prevent COVID-19 or any other disease with competent and reliable scientific knowledge would require one or more human clinical trials with several "critical features," including: placebo-control; double-blinding; randomization, with an appropriate outcome measures and a large enough sample population (to ensure that the sample population is representative of the treatment population, appropriate for the health claims made, and large enough to ensure statistical power); that has appropriate statistical analysis of the data; and that shows statistically and clinically significant results. Ex. 1 ¶¶ 19-30.

Dr. McCormack searched the literature and found only one published study of Earth Tea, which related to COVID-19. Ex. 1 ¶¶ 33-34. His review of the study reflected that it had voluminous deficiencies in nearly all of the above criteria. Ex. 1 at ¶¶ 35-44. The study was not placebo-controlled, not blinded, not randomized, had "unacceptably vague" stated goals and improperly described outcome measures, an insufficiently-small patient population of 15 participants, as opposed to the hundreds of thousands of participants needed for a properly-designed study, and "extremely poor data collection and reporting" with unintelligible data analysis. Ex. 1. at ¶¶ 35-39. In addition, the trial was published in a low-quality journal, and did not even examine Earth Tea in the context of prevention of COVID-19. Ex. 1 ¶¶ 40-43. As a result, Dr. McCormack opined that this publication was "completely inadequate to substantiate any claims that Earth Tea is effective against COVID-19." Ex. 1 ¶ 68.

Dr. McCormack also examined customer testimonials and Defendant's unpublished "independent research" relating the efficacy of Earth Tea, which also contained numerous scientific deficiencies. Ex. 1 ¶¶ 44-66. Based on his review of these materials and his education, training, and experience, Dr. McCormack concluded there was not "any reliable scientific evidence that would substantiate any health claims for Earth Tea" relating to COVID-19 or otherwise. Ex. 1 ¶ 67.

Dr. Daniel Dos Santos has Doctorates of Pharmacy and Philosophy and has been an Interdisciplinary Scientist at FDA roughly 14 years. Ex. 2 (Dr. Dos Santos Expert Report) at 1. His job responsibilities include reviewing product labeling and searching publicly-available scientific and medical literature to determine whether a product is a drug, a new drug, or an unapproved new drug under the FDCA. Through his professional experience and training, he is knowledgeable about FDCA's requirements for drugs, new drugs, and unapproved new drugs; what constitutes "disease claims" – claims that a product is intended for use in during, treating, or preventing a disease; criteria for adequate, well-controlled clinical trials; the standards for evaluating whether a drug is generally recognized as safe and effective by qualified experts for its intended use; and the determination of whether a drug is approved by FDA for its intended use. Ex. 2 at 1. He considered three core questions: (1) Is Earth Tea a drug?; (2) Is Earth Tea a new drug?; and (3) Is Earth Tea an unapproved new drug?

Dr. Dos Santos started by reviewing the language of 21 U.S.C. § 321(g)(1), which provides that "articles intended for use in the cure . . . treatment, or prevention of disease in man" are drugs. Dr. Dos Santos noted that intended use can be determined by labeling, which includes advertising and promotional claims about the product. Ex. 2 at 2. Dr. Dos Santos further noted that using a disease claim in labeling causes a product to be a drug under the FDCA. Ex. 2 at 2.

Based on his review of hundreds of Defendant's statements in B4B Earth Tea's labeling, Dr. Dos Santos concluded that Earth Tea's labeling states that Earth Tea is intended for use in curing, treating, and preventing "a wide variety of diseases, ranging from COVID-19 to several types of Cancer and HIV," and therefore Earth Tea is a drug. Ex. 2 at 2-3.

The applicable federal statute provides that a drug is a "new drug" when it is "not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling ['GRAS/E']." Ex. 2 at 3 (quoting 21 U.S.C. § 321(p)(1)). Section 321(p)(1) provides that, to be considered GRAS/E, there must be published "adequate and well-controlled clinical investigations to establish the products safety and effectiveness," and "experts must generally agree, based on those published studies, that the product is safe and effective for its intended uses." Ex. 2 at 4. The federal regulation that provides the standard for determining GRAS/E sets out the requirements for adequate and well-controlled clinical investigations, which include: a sufficient number of study participants; control group(s), *i.e.,* placebo-control; minimization of bias, usually through randomization and double-blinding; and sufficient analysis of the results to assess the treatment's effects. Ex. 2 at 4.

Dr. Dos Santos's search of the published literature revealed that there was only one published study of Earth Tea. Ex. 2 at 4-6. Upon reviewing of the publication, Dr. Dos Santos concluded that the non-placebo-controlled, non-randomized, non-blinded 15-person study "did not meet any of the[] requirements" of the applicable regulation. Ex. 2 at 6-9. Because there were no well-controlled clinical trials to support a determination of GRAS/E, Dr. Dos Santos concluded that B4B Earth Tea was not GRAS/E for any intended use and was therefore a new drug. Ex. 2 at 3, 9.

After acknowledging that the FDCA provides that new drugs cannot be introduced into interstate commerce without an FDA-approved application, Dr. Dos Santos searched the applicable FDA databases to determine whether there had been any applications or approvals for Earth Tea; finding none, he concluded that Earth Tea is an unapproved new drug. Ex. 2 at 9-10.

In his motion, Dkt. 56, Defendant moves that the Court (1) Dismiss the United States' expert reports based on his claims that they are "opinion based" and because the experts did not generate new scientific evidence; and (2) Order the United States to conduct empirical testing of Earth Tea. The law of the case forecloses Defendant's arguments, which the Court has already considered and rejected. Moreover, Defendant's motion is founded upon mischaracterizations of the United States' expert reports and unsupported by applicable legal authority.

In his other recent motion, Dkt. 55 at 5, Defendant also briefly repeats assertions and requests relating to both of the United States' experts that are redundant with those in Defendant's instant motion: Dkt. 56. For the reasons provided in the United States' opposition herein, these assertions and requests in both motions should be rejected. Defendant's motion is without merit and should be denied.

II. THE LAW OF THE CASE FORECLOSES DEFENDANT'S ATEMPT TO RELITIGATE MATTERS THE COURT ALREADY DECIDED AGAINST HIM

Defendant's argument that the United States' expert reports should be dismissed based on his assertion that they are "opinion-based" and not based on scientific data or information is an argument Defendant already made and lost. On August 20, 2024, Defendant stated to the Court:

> Recently at our previous conference the plaintiff was told to submit their expert report[s] and I was told I could counter with scientific data. The recent submission [of expert reports] from the plaintiff was not scientific data or scientific information it was opinion based. . . . I would like to request that the plaintiff's expert report[s] be denied . . . .

Dkt. 52 (Def's Ltr. Request for Ext'n) at 2. On August 21, 2024, the Court issued a minute entry order denying Defendant's request: "The [Defendant's] request to exclude plaintiff's expert report because it contains opinions is denied."[1] Notwithstanding the Court's rejection of Defendant's prior request, Defendant's instant motion repeats the same argument and requests the same relief. Dkt. 56 at 2-4. Thus, Defendant's request is barred by the law of the case.

While the Court is permitted to reconsider its own decisions prior to final judgment, "'[t]he law of the case doctrine commands that 'when a court has ruled on an issue, that decision should generally be adhered to by that court in subsequent stages in the same case' unless 'cogent and compelling reasons militate otherwise.' . . . We may depart from the law of the case for 'cogent' or 'compelling' reasons including an intervening change in law, availability of new evidence, or 'the need to correct a clear error or prevent manifest injustice.'" *Johnson v. Holder*, 564 F.3d 95, 99-100 (2d Cir. 2009) (*quoting United States v. Quintieri,* 306 F.3d 1217, 1225, 1230 (2d Cir.2002)); *accord Pescatore v. Pan Am. World Airways, Inc.*, 97 F.3d 1, 8 (2d Cir. 1996).

Defendant's motion fails to identify any such cogent or compelling reasons; to the contrary, Defendant has put forth literally the same legal argument the Court already rejected. Thus, Defendant's request should be denied.

[1] Local Civil Rule 6.3 provides that, "[u]nless provided by the court or by statute or rule . . ., a notice of motion for reconsideration must be served within 14 days after the entry of the Court's order being challenged." Lc. Civ. R. 6.3. Defendant's motion, which was served more than a month after the court's prior ruling that it challenges, should be denied because it fails to meet the deadline set forth in Local Rule 6.3.

III. DEFENDANT'S MOTION TO DISMISS THE UNITED STATES' EXPERT REPORTS BECAUSE THEY CONTAIN OPINIONS AND NO NEW SCIENTIFIC DATA IS BASELESS AND SHOULD BE DENIED

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, the Supreme Court set out the standard to be applied by federal courts in their "gatekeeping role" of determining whether scientific evidence is sufficiently reliable and relevant to be considered by the fact-finder, stating: "Faced with a proffer of expert scientific testimony, then, the trial judge must determine . . . . [whether] an expert's testimony both rests on a reliable foundation and is relevant to the task at hand. Pertinent evidence based on scientifically valid principles will satisfy those demands." 509 U.S. 579, 593-94, 597 (1993).

A. The United States' Expert Reports Are Based on Systematic Reviews of the Available Evidence Using Well-Established and Reliable Scientific Principles

As noted in Section I, the opinions of Drs. McCormack and Dos Santos are based on well-established scientific techniques and principles and tailored to the issues in this case. They are thus both reliable and relevant. Each of the United States' experts set out his methodologies, which are grounded in accepted science and, in Dr. Dos Santos's case, the requirements specified in the applicable statutes and regulations. Ex. 1 ¶¶19-32 (setting out the criteria experts in the field require to substantiate claims that Earth Tea can treat, cure, or prevent COVID-19 or other diseases); Ex. 1 ¶ 52 ("Over the last 100 years, researchers have developed the scientific method as a way of seeking answers to questions by observing and asking scientific questions and then seeking answers to those questions by doing properly designed tests and experiments. Having a knowledge of this method is essential when one is developing a new medical treatment."); Ex. 2 at 2-5, 9-10 (setting out the statutory and regulatory provisions and established scientific methods used to determine whether a product is a drug, a new drug, and an unapproved new drug).

Both experts examined hundreds of Defendant's website and social media statements that claimed that Earth Tea is an effective as treatment, cure, and/or prevention of COVID-19 and other diseases. Ex. 1 ¶¶ 13-14; Ex. 2 at 2-3; 14-19. Both experts conducted systematic searches for all published scientific research relating to Earth Tea, and both exhaustively reviewed and critiqued the only extant published study. Ex. 1 ¶¶ 33-44, 62-64; Ex. 2 at 5-9. Both experts analyzed Defendant's deposition testimony and the exhibits thereto, which included extensive examination about this study, and Defendant's "independent research" relating to COVID-19 and other diseases. Ex. 1 ¶¶ 45-66; Ex. 3 (Supplement to Expert Report of Dr. Dos Santos) at 2.

Based on his review, Dr. McCormack opined that there was not "any reliable scientific evidence that would substantiate any health claims for Earth Tea," including any health claims relating to COVID-19. Ex. 1 at 67-68. Based on his review, Dr. Dos Santos opined that the single published study relating to Earth Tea was "insufficient" and had little or no scientific impact, that Earth Tea was not generally accepted as safe and effective for any intended use, and that Earth Tea was an unapproved new drug. Ex. 2 at 2-4, 9-10. The experts' opinions, which were formed by their application of established scientific knowledge and principles to the available evidence, are both reliable and highly relevant to central issues in this case.

B. Defendant's Motion is Based on Misrepresentations of the United States' Expert Reports

Defendant mischaracterizes both of the United States' expert reports by stating that they "claim that B4B Earth Tea is ineffective." Dkt. 56 at 1; *see also id.* at 1 (claiming that the United States' expert reports "challenge the efficacy of B4B Earth Tea" and "claim that the product is

ineffective.").[2] Neither expert report contains any such claim, because the United States' allegations in this case do not require it to prove that Earth Tea is ineffective. As their reports make clear, these experts' opinions focus on whether Defendant's had adequate scientific support for the health claims he made; not, as Defendant asserts, whether Earth Tea actually works.

Defendant also claims that both the United States' experts "reached their conclusions based solely on: Social media posts[;] Customer reviews[; and] Anecdotal evidence." Dkt. 56 at 2; *id.* at 3 ("The expert reports submitted by the Plaintiff are based entirely on opinions formed from observational data (such as reading social media posts and watching consumer review videos)."); *see also id.* at 2 (claiming that Dr. McCormack's "conclusions are based solely on social media posts and customer reviews" and that Dr. Dos Santos "failed to conduct *or review* any scientific tests or clinical trials.") (emphasis added).

These claims are false. As reflected in the United States' expert reports themselves, both experts reviewed the sole published study regarding Earth Tea, as well as Defendant's testimony and exhibits thereto reflecting his "independent research" relating to the efficacy of Earth Tea and his admission that he made dozens of public claims that Earth Tea is effective against COVID-19 and various other diseases. Ex. 1 ¶¶ 35-66; Ex. 2 at 6-9; Ex. 3 at 2. As their reports make clear, Dr. McCormack used his extensive knowledge, experience and expertise in the field of evidence appraisal to assess and analyze Defendant's health claims in the context of the scientific evidence regarding Earth Tea, and Dr. Dos Santos employed his significant hands-on experience reviewing product labeling and scientific literature to analyze Defendant's health

[2] Defendant's mischaracterization of the experts' opinions is illustrated by his subsequent acknowledgement that "Dr. McCormack asserts that B4B earth Tea *has not been scientifically proven* effective." Dkt. 56 at 2.

claims in the context of the applicable statutory and regulatory provisions relating to drugs. Ex. 1 ¶¶ 1-7, 11-68; Ex. 2 at 1-10.

C. Defendant's Argument that "Opinion Based" Expert Reports are Improper Reflects Defendant's Fundamental Misunderstanding of Expert Discovery

Defendant requests that the Court "dismiss the expert reports [submitted by the United States] as these reports lack scientific evidence and are based on opinion rather than verifiable data," Dkt. 56 at 4, and argues that "[t]his Court should not base its judgment on speculative or opinion-based reports." *Id.* at 2. It is black-letter law and a core tenet of civil discovery that opinions from experts, far from being prohibited or discouraged, are not only accepted,[3] but required. *See* Fed. R. Civ. P. 26(a)(2)(B)(i) (providing that expert reports in civil cases "must contain: (i) a complete statement of all the opinions the witness will express").

Thus, Defendant's attack of expert opinions as somehow improper or *per se* unreliable is both meritless and illustrative of the frivolous nature of Defendant's motion and its arguments.

D. Defendant's Argument that the United States' Experts Lack a Reliable Scientific Methodology Solely Because They Did Not Affirmatively Conduct Empirical Testing or Studies of the Product Lacks Any Legal Basis

Defendant argues that the opinions of the United States' experts are unreliable and should be dismissed solely because the experts did not generate new scientific evidence through affirmative empirical testing or research.[4] Dkt. 56 at 2 (arguing that neither of the United States' expert reports are reliable, solely because "they lack laboratory testing, clinical trials, or scientific validation."); *see id.* at 2 (criticizing Dr. McCormack's conclusions as being "without any direct evaluation of the actual product in question" and containing "no laboratory tests,

[3] *See, e.g.,* Fed. R. Evid. 702 (providing that "a witness qualified as an expert . . . may testify . . . in the form of an opinion or otherwise.").

[4] Defendant's argument, even if it had been valid, would have been relevant not to the expert reports' admissibility, but rather the weight the fact-finder accorded them.

clinical trials, or peer-reviewed studies to support them); *see id.* at 2 ("Dr. Dos Santos's analysis is purely speculative, offering no rigorous testing or objective research to support his claims about B4B Earth Tea's efficacy."); *see id.* at 1 ("Without empirical testing, the reliance on these opinion-based reports may result in a wrongful conviction . . . ."). Dkt. 56 at 3 ("The Defendant argues that these reports should be rejected, and only reports grounded in proper scientific methodology—including lab results and controlled testing—should be considered."). Defendant's argument is perverse and devoid of legal support.[5]

The United States' experts applied their specialized knowledge and experience to review and critically analyze the sole published study of Earth Tea, as well as Defendant's unpublished "independent research," and concluded that, in toto, they are insufficient to support the efficacy of Earth Tea against COVID-19 or any other disease. Exs. 1-3. Having done so, there is no valid basis for Defendant to claim that the United States' experts should or must *generate additional evidence* by conducting further studies or testing of the product. Defendant cites absolutely no legal or scientific basis for this claim, and the United States is not aware of any.

None of the cases cited by Defendant support his position. While *Daubert v. Merrell Dow Pharmaceuticals, Inc.* provides that expert testimony must be based on a reliable scientific methodology, Dkt. 56 at 2, the facts of the *Daubert* case undercut Defendant's position. 509 U.S. 579 (1993). In *Daubert*, the Defendant's expert—like the United States' experts in this case—did not conduct any affirmative testing or scientific study of the substance at issue, but rather

[5] Defendant's argument appears to be based on his incorrect supposition that such testing is required to support the United States' claims. In Defendant's November 25, 2023 Motion to Compel Discovery, he moved to compel documents that the United States had informed him that it did not have, including "test, research or . . . evidence that was done to supports [sic] Plaintiff's claims" and "lab result, research results or independent lab analysis done to support deceptive claims." Dkt. 35 at 3. For obvious reasons, Defendant's motion to compel was unsuccessful.

reviewed all the published studies on the substance and concluded that none of them had found the substance to cause the effects the opposing party claimed. 509 U.S. at 582. No one – neither the Court nor a party, contested Defendant's expert's "characterization of the published record regarding" the product or took issue with the reliability of his opinions. *Id.* at 583. Thus, the underlying facts of *Daubert* contradict Defendant's claim—borne out of thin air—that for expert testimony to be scientifically reliable, it must include affirmative testing or study. In *General Electric Co. v. Joiner*, 522 U.S. 136 (1997), the court's exclusion of expert testimony had absolutely nothing to do with whether the experts conducted affirmative research or study of the substances in question, and so is irrelevant.[6]

None of the cases cited by Defendant contain a single statement by a court indicating that expert opinions are unreliable because they do not include affirmative testing or research. Given the absence of any legal support for his position, Defendant's request that the Court exclude the United States' experts on this basis should be denied.

IV. DEFENDANT'S REQUEST THAT THE COURT ORDER THE UNITED STATES TO TEST DEFENDANT'S PRODUCT LACKS A LEGAL BASIS

Next, Defendant requests that the Court order the United States to perform scientific testing of Defendant's product:

> To avoid wrongful conviction, the Defendant requests that the Plaintiff be required to conduct proper scientific testing, such as an ELISA test (Enzyme-Linked Immunosorbent Assay). . . . In this case, and ELISA test which is the gold standard for laboratory **would provide objective and empirical evidence to detect whether Earth Tea has any effects on the body's immune response or interaction with viral elements, such as COVID-19**.

[6] Defendant cites *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999) solely for the proposition that the Court's gatekeeper function applies to types of specialized knowledge other than scientific knowledge. Dkt. 56 at 3. This point is irrelevant, because the opinions of the United States' experts are based on scientific knowledge.

Dkt. 56 at 3 (emphasis added). In making this request, Defendant not only acknowledges the current lack of—hence the need for—objective and empirical evidence establishing that Earth Tea has any effect on the immune system or COVID-19, but he also requests that the United States be **required to** spend the time and money to create this evidence about Defendant's product, after Defendant has for years marketed it as "100% effective" and "guaranteed." Ex. 4 at Tr. 76:14-77:20; 96:22-97:5; 99:6-100:9; 112:3-19; 114:3-24; 116:2-117:17; 118:7-9; 118:23-119:22; 120:15-121:11; 123:24-125:8; 161:5-163:9. Defendant's request thus seeks to turn the drug approval process and its long-standing statutory and regulatory underpinnings on their head, by shifting onto the federal government the manufacturer's burden to study and test its product to establish its effectiveness.

Needless to say, Defendant's request fails to cite any supporting legal authority, and the United States does not believe any exists. Moreover, as with the "independent scientific report" that Defendant indicates that he is preparing, Dkt. 55 at 5, any new testing or study would be irrelevant to the United States' claims in this case, which allege that Earth Tea was an unapproved new drug *at the time Defendant distributed it* and that Defendant lacked sufficient scientific evidence to substantiate his health-related marketing claims *at the time he made them*. Thus, the testing Defendant requests that the United States be ordered to conduct would have *no effect* on the Court's analysis of whether Defendant violated the Federal Food, Drug, and Cosmetic Act, the Federal Trade Commission Act, or the COVID-19 Consumer Protection Act.

CONCLUSION

For the reasons provided above, Defendant's motion is meritless and should be denied.

Dated: October 1, 2024 Respectfully submitted,

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